PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Douglas G. McNeel

Art Unit: 1632

Application No.: 10/669,474

Examiner: Louis D. Lieto

Filed: September 25, 2003

Attorney Docket: 960296.00333

Title: METHODS AND COMPOSITIONS FOR TREATING PROSTATE CANCER USING DNA VACCINES

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner For Patents
Alexandria, VA 22313-1450

Dear Sir:

I, Douglas G. McNeel, on oath say and declare that:

1. I am the same Douglas G. McNeel who is the named inventor of the above-identified patent application. I am currently an assistant Professor of Medicine at the University of Wisconsin-Madison and a member of the Experimental Therapeutics and Immunology and Immunotherapeutics groups at the University of Wisconsin Comprehensive Cancer Center. I obtained my PhD degree in Biochemistry and Molecular Biology in 1992 and my MD degree in 1994, both from University of Chicago. I completed my Medical Oncology fellowship at the University of Washington and Fred Hutchinson Cancer Research Center in 2000 and joined the faculty of the University of Wisconsin-Madison in 2001. During my time at the University of Washington, I spent four years as a postdoctoral fellow and junior faculty member with the Tumor Vaccine Group, studying the immunology of human prostate cancer. At the University of Wisconsin-Madison, I continue to focus my research on the immunology of prostate cancer with the goal of developing tumor vaccines for prostate cancer. I have published many articles on this subject. Recently, I was invited to write an article describing a clinical trial currently underway using the DNA vaccine described in this application. A copy of my Curriculum Vitae is attached as Exhibit A.

2. I have reviewed the Office Action issued in this matter by the U.S. Patent and Trademark Office on April 4, 2006. I understand that claims 1, 2, and 7-9 are rejected for the alleged lack of enablement. This Declaration is submitted to provide evidence that claims 1, 2, and 7-9 are enabled.

3. At my direction and under my supervision, members of my laboratory conducted the following three experiments which show that immunization with pTVG-HP or pTVG-RP elicited both therapeutic (experiment 1) and protective (experiment 2) anti-tumor (prostate) responses. Further, immunization with pTVG-HP or pTVG-RP elicited cytotoxic-T-lymphocyte (CTL) response (experiment 3). As provided in the application, pTVG-HP is a vector carrying the coding sequence for the human prostatic acid phosphatase (PAP) and pTVG-RP is a vector carrying the coding sequence for the rat PAP, both having the backbone of the parent, control pTVG4 vector. A detailed description of the pTVG4, pTVG-HP, and pTVG-RP vectors can be found at paragraphs [0078]-[0081] on pages 32 and 33 of the application.

4. In experiment 1, male Copenhagen rats were treated on day 0 with 10^4 Mat-Lu cells (transplantable prostate tumor cells) implanted subcutaneously in Matrigel (BD Pharmingen). Animals were treated in random fashion, to not bias tumor implantation, and then subsequently assigned to treatment groups. Animals were then immunized on days 1 and 15 with 100 μg pTVG-HP (n=6), pTVG-RP (n=6), or PBS (n=3) only. Bidimensional tumor measurements were obtained beginning on day 23. Fig. 1 attached (Exhibit B) shows the mean and standard deviation of the tumor volume measurements for all animals in each treatment group. As can be seen in Fig. 1, immunization with pTVG-HP or pTVG-RP elicited therapeutic anti-tumor response *in vivo*.

5. In experiment 2, male Copenhagen rats were immunized four times with pTVG4 (n=10), pTVG-HP (n=10), or pTVG-RP (n=10). Two weeks after the last immunization, animals were challenged with 10^6 Mat-Lu cells administered subcutaneously. Fig. 2 attached (Exhibit C) is a Kaplan Meier analysis with events determined once bidimensional tumor sizes measured 10 cm^3 in size. As can be seen in Fig. 2, immunization with pTVG-HP or pTVG-RP elicited protective anti-tumor response *in vivo*.

6. In experiment 3, male Copenhagen rats received 10^4 MatLu cells administered subcutaneously on day 1, followed by two intradermal immunizations (on days 2 and 16) with 100 μg of control pTVG4 plasmid (n=6), pTVG-HP (n=6) or pTVG-RP (n=6). Animals were

sacrificed on day 45, and splenocytes pooled from animals per group. Splenocytes were stimulated *in vitro* with irradiated MatLu cells (120 Gy) in a 10:1 ratio for 6 days with the addition of 10 U/ml rIL-2 on day 4. CTL activity to MatLu target cells was detected by lactate dehydrogenase (LDH) release (Cytox 96 kit, Promega) on day 7. Fig. 3 attached (Exhibit D) shows the mean and standard deviation of % specific lysis for triplicate samples against the Mat-Lu targets using effector cells from animals immunized with pTVG4, pTVG-HP, or pTVG-RP. As can be seen in Fig. 3, immunization with pTVG-HP or pTVG-RP elicited CTL.

7. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated this 26th day of May 2006.

Douglas G. McNeel

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EXHIBIT A

DOUGLAS G. McNEEL, M.D. Ph.D.
CURRICULUM VITAE

CURRENT ADDRESSES:

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University of Wisconsin Comprehensive Cancer Center
K4/518 Clinical Science Center
600 Highland Avenue
Madison, WI 53792
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EDUCATION:

1986 B.A.	Chemistry, Music; Whitman College, Walla Walla, WA
1991 M.S.	Biochemistry, Molecular Biology; University of Chicago, Chicago, IL
1992 Ph.D.	Biochemistry, Molecular Biology; University of Chicago, Chicago, IL Laboratory of Fuyuhiko Tamanoi, PhD – Thesis "Identification and characterization of TRF1, a DNA-binding protein in a yeast linear DNA plasmid system"
1994 M.D.	University of Chicago – Pritzker School of Medicine, Chicago, IL

POSTGRADUATE TRAINING:

1994 – 1996	Residency in Internal Medicine, University of Washington, Seattle, WA Clinical Investigator Pathway
1996 – 1997	Clinical Fellow in Oncology, University of Washington, Seattle, WA.
1997 – 1999	Senior Postdoctoral Fellow, Division of Medical Oncology, University of Washington, Seattle, WA. Laboratory of Dr. Mary L. (Nora) Disis

FACULTY POSITIONS AND ACADEMIC APPOINTMENTS:

1999 – 2001	Acting Instructor, Division of Oncology, University of Washington, Seattle, WA
2001 –	Assistant Professor of Medicine, Section of Medical Oncology, University of Wisconsin, Madison, WI

HOSPITAL POSITIONS HELD:

1999 – 2001	Staff attending physician, University of Washington Medical Center
2001 –	Staff attending physician, University of Wisconsin Hospital and Clinics

HONORS AND AWARDS:

Honors at Entrance, Whitman College, Walla Walla, WA, 1982
Phi Beta Kappa, Whitman College, 1985
Mortar Board, Whitman College, 1986
Outstanding Senior Chemistry Award – American Chemical Society, Whitman College, 1986
Graduation *summa cum laude*, Whitman College valedictorian, 1986
Honors in major study, Chemistry, 1986
Honors in major study, Music, 1986
National Institutes of Health Medical Scientist Training Program Award, 1987-1994
American Association for Cancer Research-AFLAC Young Investigator Award, 1999
American Association for Cancer Research-AFLAC Young Investigator Award, 2000
American Association for Cancer Research-AFLAC Scholar in Training Award, 2001

HONORS AND AWARDS (continued):

Howard Hughes Medical Institute – University of Wisconsin Faculty Development Award, 2001
Research highlighted in Congressionally Directed Medical Research Program Annual Report, 2005

BOARD CERTIFICATION:

National Board of Internal Medicine, 1997
National Board of Internal Medicine, Medical Oncology, 2001

MEDICAL LICENSES TO PRACTICE:

1994 – 2002	Washington state
2001 –	Wisconsin state

PROFESSIONAL ORGANIZATIONS:

American Association for Cancer Research, Active Member
American Society of Clinical Oncology, Associate Member
American Society of Gene Therapy, Associate Member
International Society for Biological Therapy of Cancer, Fellow
American Association of Immunologists, Active Member

NATIONAL COMMITTEE MEMBERSHIPS / GRANT PANELS:

2001	Scientific reviewer: 2001 Department of Defense Breast Cancer Research Program Centers of Excellence and Clinical Translational Research Section
2002 – 2005	Scientific Review Board: NIH National Gene Vector Laboratory Program
2003	Scientific reviewer: 2003 Department of Defense Breast Cancer Research Program Immunological Sciences Section
2004	Scientific reviewer: 2004 Department of Defense Breast Cancer Research Program Immunological Sciences Section
2004	Ad hoc scientific reviewer: NIH National Cancer Institute, Innovative Methods and Technologies study section
2005	Scientific reviewer: NIH National Cancer Institute, Innovative Methods and Technologies study section member
2005 – present	Member, American Society of Clinical Oncology Cancer Education Committee, Genitourinary Cancer Track
2005	Scientific reviewer: 2005 Department of Defense Breast Cancer Research Program Immunological Sciences Section
2006	Scientific reviewer: NIH National Cancer Institute, SPORE program study section member

INVITED JOURNAL REVIEWER:

American Journal of Clinical Oncology
Cancer Immunology and Immunotherapy
Cancer Research
Clinical Cancer Research
Genetic Vaccines and Therapy
Journal of Clinical Oncology
Journal of Urology
Molecular Cancer Therapeutics
The Prostate
Urology
Vaccine

INVITED PRESENTATIONS AND SEMINARS AT NATIONAL AND REGIONAL MEETINGS:

1. **McNeel DG** (6/9/2006) "Vaccines in Prostate Cancer." *Cancer Pharmacology Seminar Series*, Madison, WI.
2. Chairman and discussant for Clinical Science Symposium "Immunotherapy in Prostate Cancer: Progress and Trials" (6/3/2006) – 2006 national meeting of the American Society of Clinical Oncology, Atlanta, GA.
3. **McNeel DG** (5/5/2006) "Update on chemotherapy for hormone refractory prostate cancer." *2006 Prostate Cancer Review: Redefining Disease Management*, Kansas City, MO.
4. **McNeel DG** (5/5/2006) "Novel targeted therapies review: Is anything moving closer to FDA approval?" *2006 Prostate Cancer Review: Redefining Disease Management*, Kansas City, MO.
5. **McNeel DG** (10/21/2005) "Immunological approaches to prostate cancer." *2005 Uehling Lectures – Prostate Cancer: State-of-the-Art Therapy*, Madison, WI.
6. **McNeel DG** (4/16/2005) "Treatments for advanced prostate cancer." *Minnesota Urological Society Annual Conference,* Northland, MN.
7. **McNeel DG**, Thomas JP, Friedl A, Lee FT, Alberti D, Wilding G (2/25/2004) "A phase I trial of MEDI-522 in patients with advanced malignancies." *NCI 2004 Cancer Therapy Evaluation Program (CTEP) Early Drug Development Annual Spring Meeting,* Bethesda, MD.
8. **McNeel DG** (10/10/2003) "Prostate cancer vaccines." University of Wisconsin Comprehensive Cancer Center Annual Conference – *UWCCC Advances in Multidisciplinary Cancer Care*, Madison, WI
9. **McNeel DG** (6/4/2002) "Issues in the diagnosis and management of prostate cancer." Kishwaukee Hospital Grand Rounds, Dekalb, IL.
10. **McNeel DG** (11/19/2001) "Vaccines for treatment of prostate cancer." University of Wisconsin Department of Urology 2001 Uehling Lectures, Madison, WI.
11. **McNeel DG** (1/3/2001) "Prostate cancer associated proteins as candidate vaccine antigens." University of Wisconsin Comprehensive Cancer Center Grand Rounds, Madison, WI.
12. **McNeel DG** (8/2/1999) "Prostate specific antigens as vaccine candidates." Fred Hutchison Cancer Research Center Seminar Series, Seattle, WA.

BIBLIOGRAPHY:

A. Peer-Reviewed Publications of Original Work:

1. Hoeppner LH, Dubovsky JA, Dunphy EJ, and **McNeel DG**. (2006) "Humoral immune responses to testis antigens in sera from patients with prostate cancer." *Cancer Immun.* [serial online] **6**:1-7.
2. Mooney CJ, Dunphy EJ, Stone B, and **McNeel DG**. (2006) "Prostate cancer presenting as dermatomyositis: Case report and immunological analysis." *Int. J. Urol.* **13**:211-217.

3. Johnson LE, Frye TP, Arnot AR, Marquette C, Couture LA, Gendron-Fitzpatrick A, and **McNeel DG**. (2006) "Safety and immunological efficacy of a prostate cancer plasmid DNA vaccine encoding prostatic acid phosphatase (PAP)." *Vaccine* **24**:293-303.
4. Zlotocha S, Staab MJ, Horvath D, Straus J, Dobratz J, Oliver K, Wasielewski S, Alberti D, Liu G, Wilding G, Eickhoff J, and **McNeel DG**. (2005) "A phase I study of a DNA vaccine targeting prostatic acid phosphatase (PAP) in patients with stage D0 prostate cancer." *Clin. Genitourinary Cancer* **4**:215-218.
5. **McNeel DG**, Eickhoff J, Lee FT, King DM, Alberti D, Thomas JP, Friedl A, Kolesar J, Volkman J, Zhang J, Hammershaimb L, Zwiebel JA, and Wilding G. (2005) "Phase I trial of a monoclonal antibody specific for $\alpha_v\beta_3$ integrin (MEDI-522) in patients with advanced malignancies, including as assessment of effect on tumor perfusion." *Clin. Cancer Res.* **11**:7851-7860.
6. Dunphy EJ and **McNeel DG**. (2005) "Antigen-specific IgG elicited in subjects with prostate cancer treated with flt3 ligand." *J. Immunotherapy* **28**:268-275.
7. Dunphy EJ, Eickhoff JC, Muller CH, Berger RE, and **McNeel DG**. (2004) "Identification of antigen-specific IgG in sera from patients with chronic prostatitis." *J. Clin. Immunol.* **24**:492-502.
8. Disis ML, Shiota FM, **McNeel DG** and Knutson KL. (2003) "Soluble cytokines can act as effective adjuvants in plasmid DNA vaccines targeting self-tumor antigens." *Immunobiology* **207**:1-8.
9. **McNeel DG**, Knutson KL, Schiffman K, Davis DR, Caron D and Disis ML. (2003) "Pilot study of an HLA-A2 peptide vaccine using Flt3 ligand as a systemic vaccine adjuvant." *J. Clin. Immunol.* **23**:62-72.
10. **McNeel D**, Rubio MT, Damaj G, Emile JF, Belanger C, Varet B, Brousse N, Hermine O and Buzyn A. (2002) "Hypereosinophilia as a presenting sign of acute graft-versus-host disease after allogeneic bone marrow transplantation." *Transplantation* **74**:1797-1800.
11. **McNeel DG**, Nguyen LD and Disis ML. (2001) "Identification of T helper epitopes derived from prostatic acid phosphatase." *Cancer Res.* **61**:5161-5167.
12. **McNeel DG**, Nguyen LD, Ellis WJ, Higano CS, Lange PH and Disis ML. (2001) "Naturally occurring prostate cancer antigen-specific T cell responses of a Th1 phenotype can be detected in patients with prostate cancer." *Prostate* **47**:222-229.
13. **McNeel DG**, Nguyen LD, Storer BE, Vessella R, Lange PH and Disis ML. (2000) "Antibody immunity to prostate cancer-associated antigens can be detected in the serum of patients with prostate cancer." *J. Urol.* **164**:1825-1829.
14. Disis ML, Knutson KL, Schiffman K, Rinn K and **McNeel DG**. (2000) "Pre-existent immunity to the HER-2/neu oncogenic protein in patients with HER-2/neu overexpressing breast and ovarian cancer." *Breast Canc. Res. Treatment* **62**:245-252.
15. Disis ML, Schiffman K, Gooley TA, **McNeel DG**, Rinn K and Knutson KL. (2000) "Delayed type hypersensitivity response (DTH) is a predictor of peripheral blood T cell immunity after HER-2/neu peptide immunization." *Clin. Cancer Res.* **6**(4):1347-1350.
16. **McNeel DG**, Schiffman KA and Disis ML. (1999) "Immunization with rhGM-CSF as a vaccine adjuvant elicits both a cellular and humoral response to rhGM-CSF." *Blood* **93**:2653-2659.
17. **McNeel DG** and Tamanoi F. (1992) "Terminal region recognition factor 1, a DNA-binding protein recognizing the inverted terminal repeats of the pGKl linear DNA plasmids." *Proc. Natl. Acad. Sci. USA* **88**:11398-11402.

B. Invited Review Articles:

1. **McNeel DG** and Malkovsky M. (2005) "Immune-based therapies for prostate cancer." *Immunol. Lett.* **96**:3-9.
2. Hegeman RB, Liu G, Wilding G and **McNeel DG**. (2004) "Newer therapies in advanced prostate cancer." *Clin. Prostate Cancer* **3**:150-156.
3. Disis ML, Knutson KL, **McNeel DG**, Davis D, and Schiffman K. (2001) "Clinical translation of peptide-based vaccine trials: The HER-2/neu model." *Crit. Rev. Immunol.* **21**:263-273.
4. **McNeel DG**, Disis ML. (2000) "Tumor vaccines for the management of prostate cancer." *Arch. Immunol. Ther. Exp.* **48**:85-93.

5. Disis ML, **McNeel DG**, Rinn K, Schiffman K, and Knutson K. (1999) "Peptide-based tumor vaccines." *Curr. Opin. Oncol. Endo. Metabol. Invest. Drugs* 1:253-259.

C. Invited, Peer-Reviewed, Book Chapters:

1. Dunphy EJ, Johnson LE, Olson BM, Frye TP, and **McNeel DG.** "New approaches to identification of antigenic candidates for future prostate cancer immunotherapy." In: Giaccone G, Schilsky R, Sondel P. eds. *Cancer Chemotherapy and Biological Response Modifiers, Annual 23.* Oxford: Elsevier Limited, 2006 (in press).
2. **McNeel DG.** "Prostate cancer antigens and vaccines, preclinical developments." In: Giaccone G, Schilsky R, Sondel P. eds. *Cancer Chemotherapy and Biological Response Modifiers, Annual 22.* Oxford: Elsevier Limited, 2005 p. 247-261.

D. Manuscripts Submitted:

1. Lalich M, **McNeel DG**, Wilding G, and Liu G. "Endothelin receptor antagonists in cancer therapy."
2. Johnson LE, Frye TP, Chinnasamy D, Chinnasamy N, and **McNeel DG**. "Plasmid DNA vaccine encoding prostatic acid phosphatase (PAP) effective in eliciting autologous antigen-specific CD8 T cells."
3. Agus DB, Sweeney C, Morris M, Mendelson D, **McNeel DG**, Ahmann F, Wang J, Dernyck M, Ng K, Lyons B, Allison D, Kattan M, Scher HI. "Efficacy and safety of single-agent pertuzumab (rhuMAb 2C4), a HER dimerization inhibitor in castration-resistant prostate cancer after progression from taxane-based therapy."
4. Zhang D, Pier T, **McNeel DG**, Wilding G, and Friedl A. "Effects of a monoclonal anti-αvß3 integrin antibody on blood vessels – a pharmacodynamic study."

E. Manuscripts in Preparation:

1. **McNeel DG**, Olson BM, Frye TP, Knutson KL, and Disis ML. "HLA-A2 CTL epitopes from prostatic acid phosphatase identified by ELISPOT."
2. Johnson LE and **McNeel DG**. "Intraarterial administration of a DNA vaccine leads to enhanced tissue expression and cellular immune responses."

F. Published Abstracts/Posters Presented at National Meetings:

1. Dubovsky J, Dunphy EJ, Stone B, **McNeel DG.** (2006) "Phage expression arrays to detect potential prostate cancer-testis antigens." *Proc. Amer. Assn. Cancer Res.* **47**:2244.
2. Schell K, Dunphy EJ, Urben C, Dresen A, Kolesar J, Liu G, Wilding G, **McNeel DG.** (2006) "Evaluation of G3139 treatment effects on peripheral blood lymphocyte numbers and function." *Proc. Amer. Assn. Cancer Res.* **47**:1308.
3. Johnson LE, Frye TP, **McNeel DG.** (2006) "Immunization of Lewis rats with a prostate cancer xenoantigen elicits predominantly xenoantigen epitope-specific T cell responses." *Proc. Amer. Assn. Cancer Res.* **47**:1174.
4. Agus DB, Sweeney CJ, Morris M, Mendelson D, **McNeel DG**, Ahmann F, Wang J, Derynck MK, Kattan MW, Scher HI (2005) "Efficacy and safety of single agent pertuzumab (rhuMAb 2C4), a HER dimerization inhibitor, in hormone refractory prostate cancer after failure of taxane-based therapy." *2005 ASCO Annual Meeting Proc.* **23**:4624.
5. Johnson LE, Frye TP, Arnot AR, Marquette C, Gendron-Fitzpatrick A, **McNeel DG** (2004) "Safety and efficacy of a prostate cancer plasmid DNA vaccine encoding prostatic acid phosphatase." *AACR – Basic, Translational and Clinical Advances in Prostate Cancer Meeting*, Bonita Springs, FL.

6. Johnson LE, Frye TP, Arnot AR, Marquette C, Gendron-Fitzpatrick A, **McNeel DG** (2004) "Safety and immunological efficacy of a prostate cancer plasmid DNA vaccine encoding prostatic acid phosphatase." *11th Annual Prostate Cancer Foundation Scientific Retreat*, Lake Tahoe, NV.
7. Hoeppner LH, Dunphy EJ, **McNeel DG** (2004) "Identification of prostate cancer-testis antigens." *Proc. Amer. Assn. Cancer Res.* **45**:5476.
8. Johnson LE and **McNeel DG** (2004) "DNA vaccine encoding a prostate-specific protein elicits CD8 T cell immunity and tissue-specific inflammation." *Proc. Amer. Assn. Cancer Res.* **45**:1244.
9. **McNeel DG**, Thomas JP, Lee FT, Friedl A, Marnocha R, Tutsch K, Binger K, Volkman J, Lakner M, Alberti D, Eickhoff J, Wilding G (2003) "A phase I trial of MEDI-522 in patients with advanced malignancies." *15th Annual EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics*, Boston, MA.
10. Dunphy EJ and **McNeel DG** (2003) "Identification of immunologically recognized prostate antigens." *10th Annual CaP CURE Scientific Retreat*, Washington, D.C.
11. Dunphy EJ, Muller CH, Berger RE, **McNeel DG** (2003) "Prostate antigen-specific immunity can be detected in some patients with chronic prostatitis." *Proc. Amer. Assn. Cancer Res.* **44**:420.
12. Dunphy EJ and **McNeel DG** (2003) "SEREX method to identify immunological responses elicited during immunomodulatory therapy." *Proc. Amer. Assn. Cancer Res.* **44**:419.
13. Johnson LE, Zhang G, Wolff JA, **McNeel DG** (2003) "Intraarterial delivery of a DNA-based vaccine elicits high levels of antigen expression and antigen-specific immunity." *Proc. Amer. Assn. Cancer Res.* **44**:886.
14. Dunphy EJ, Muller CH, Berger RE, **McNeel DG** (2002) "Identification of serological antigens in patients with chronic prostatitis as potential tumor antigens in prostate cancer." *9th Annual CaP CURE Scientific Retreat*, Washington, D.C.
15. **McNeel DG**, Knutson KL, Schiffman K, Davis DR, Caron D (2002) "Phase I study of a peptide-based vaccine targeting HER-2/neu in patients with advanced stage prostate cancer." *Proc. Amer. Assn. Cancer Res.* **43**:561-562.
16. **McNeel DG**, Nguyen LD, Cardon K, Nelson PS, Gottesman, J, Disis ML (2001) "Identification of two serologic tumor antigens in patients with prostate cancer." *Proc. Amer. Assn. Cancer Res.* **42**:156.
17. **McNeel DG**, Knutson KL, Disis ML (2001) "Identification of PAP-specific MHC class I peptide epitopes by screening patients with prostate cancer by IFNγ ELISPOT." *Proc. Amer. Assn. Cancer Res.* **42**:277.
18. **McNeel DG**, Nguyen LD, Disis ML (2000) "T cells derived from patients with prostate cancer secrete IFNγ in response to stimulation with prostate cancer antigens." *Proc. Amer. Assn. Cancer Res.* **41**:880.
19. **McNeel DG**, Nguyen LD, Disis ML (2000) "Identification of potential CD4+ T helper epitopes derived from the protein sequence of prostatic acid phosphatase (PAP)." *Proc. Amer. Assn. Cancer Res.* **41**:699.
20. **McNeel DG**, Vessella R, Lange PH, and Disis ML. (1999) "Antibody immunity to prostate cancer antigens can be detected in patients with prostate cancer." *Proc. Amer. Assn. Cancer Res.* **40**:353.
21. **McNeel DG** and Disis ML. (1999) "T cell immunity specific for prostatic acid phosphatase (PAP) results in a destructive prostatitis in a rodent model." *Proc. Amer. Assn. Cancer Res.* **40**:256.
22. **McNeel DG** and Tamanoi F. (1991) "pGKl2 from the yeast DNA 'killer' plasmid system encodes a small, basic DNA-binding protein which recognizes the inverted terminal repeats of both pGKl1 and pGKl2." *Eukaryotic DNA Replication Meeting*, Cold Spring Harbor, NY.

EXHIBIT B

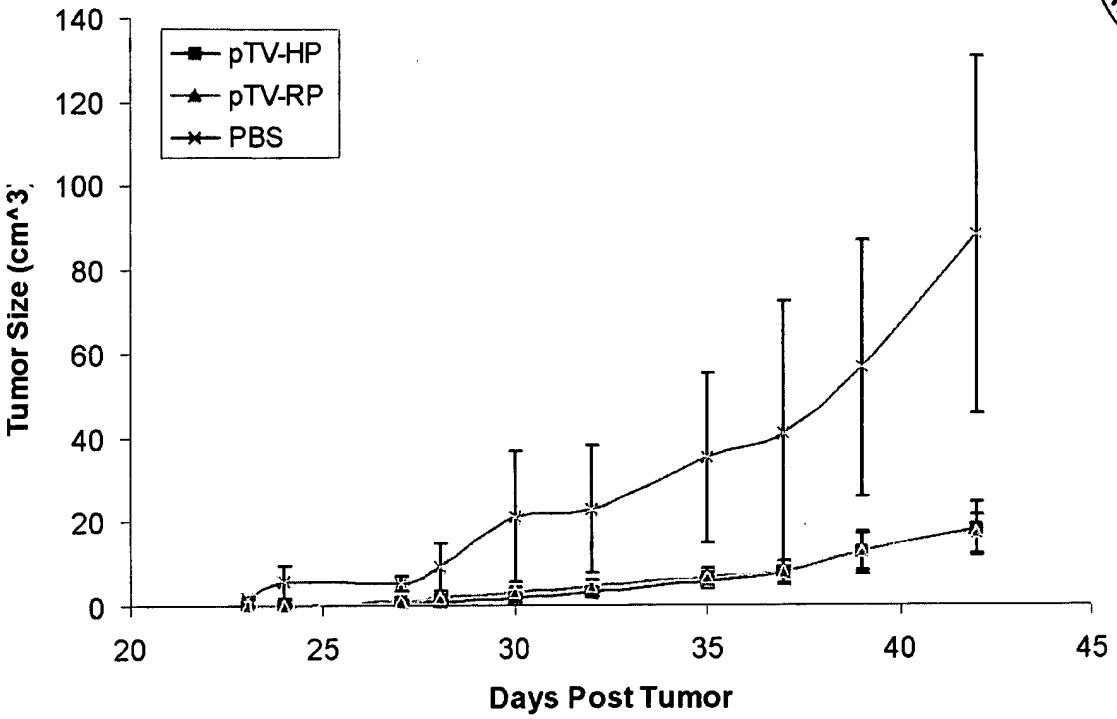

FIG. 1

EXHIBIT C

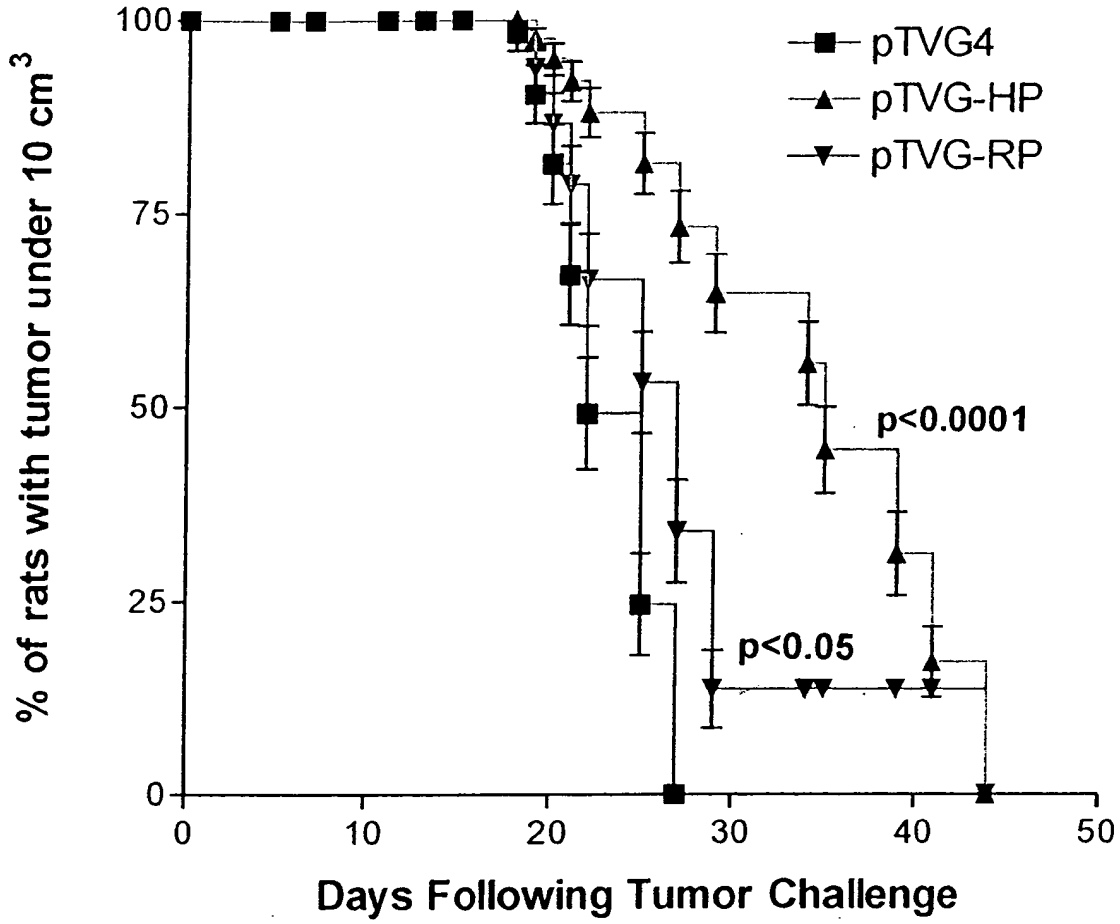

FIG. 2

EXHIBIT D

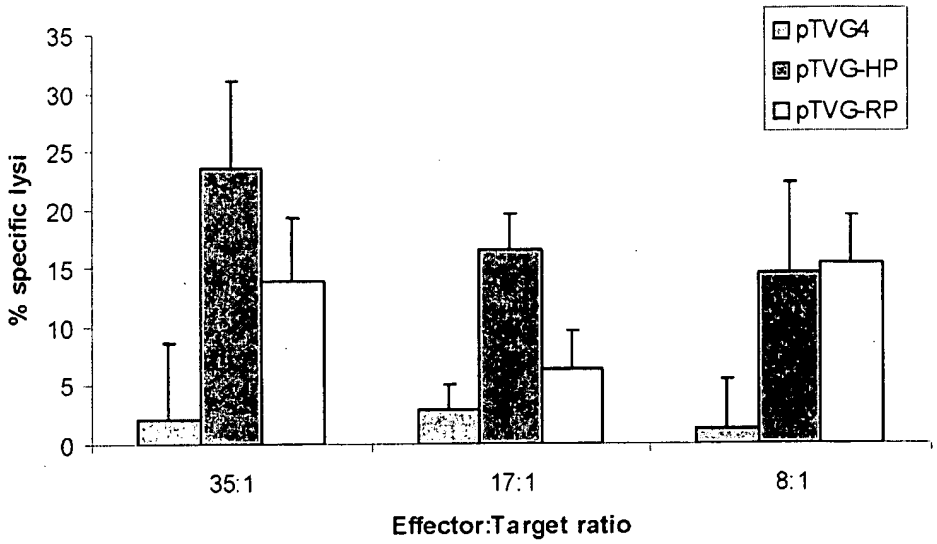

FIG. 3